

being required under the general authority of section 8(a) of the Act, to require submission of information necessary for administration of TSCA.

EPA intends to use the production volume data to help set priorities for implementing TSCA. In particular, EPA will initiate subsequent phases for reporting on chemical substances selected in part on the basis of their production volume. Section 710.5(d)(4) requires reporting of production in fairly broad ranges. (See comment 6.) Because manufacturers should know generally how much of a chemical substance they manufacture on an annual basis, EPA does not anticipate that this requirement will significantly delay reporting. Combining reporting of production with reporting of chemical substance identities is far more efficient, in terms of time and resources both for EPA and the industry, than requiring separate reporting. Saving many months of additional effort clearly justifies the few months of delay in the publication of the initial inventory.

*Comment 5:* Production volume data are available elsewhere, notably from trade associations and other governmental agencies. EPA also has authority under Air and Water Acts to gather the data.

*Response:* The production data available to EPA from other sources are inadequate in several respects. Other government agencies, such as the International Trade Commission, believe they are not permitted, by statute, to disclose confidential production data to EPA. Further, these data are often collected for groups of chemical substances, and not for discrete chemical substances. While EPA has gathered certain data for several hundred chemical substances under its other authorities, these substances represent only a fraction of those EPA anticipates will be reported for the inventory. Only by collecting production information along with the chemical identities as they are reported for the inventory will EPA be assured of having a comprehensive indication of production for these substances.

*Comment 6:* Several commenters suggested that production volume data should be reported in broad ranges because statistical analysis shows that aggregate totals will provide enough accuracy for EPA to set relative priorities. Others recommended that production volume data should be reported to one or two significant figures or to within a specified percentage.

*Response:* As provided in § 710.5(d)(4), the Administrator has determined that reporting of production volume in ranges is adequate for the purposes of these regulations. The ranges established by these regulations are in terms of powers of ten, except in the upper volumes where the difference between the lower and upper limits of the ranges would be too great. In subsequent section 8(a) reporting requirements, when the Agency has identified a particular interest in a chemical, the Administrator may request production volume information with greater specificity.

*Comment 7:* Total production volume information for a company should be required, rather than site specific information.

*Response:* The Administrator disagrees with this comment. In order to establish an adequate profile of the chemical industry and properly assign agency resources, particularly the agency's regional resources, production information is necessary on a site specific basis.

*Comment 8:* Production volume information on intermediates, raw materials, and byproducts should not be required.

*Response:* Section 710.5(d)(4) of these regulations will require reporting of production volume information on intermediates. As discussed in response to comment 67 below, the term "intermediate" has been de-

fined to include only those chemical substances that are intentionally removed from the equipment in which they are manufactured. The Agency expects that a manufacturer will be able to estimate the range of production volume of the intermediates which he isolates in this manner.

Under these regulations, manufacturers are not required to report the identity of purchased raw materials or byproducts which have no commercial value. Accordingly, a manufacturer would not be required to report the production volume of these substances.

*Comment 9:* EPA should not set its priorities on the basis of production volume alone.

*Response:* EPA recognizes that priorities under TSCA cannot be set on the basis of any single factor. The production data obtained under these regulations will be only one factor in selecting chemical substances for attention. Production volume information is important because it gives some indication of the potential for human and environmental exposure. Other information such as the toxicity of the substance, its uses, and byproducts will, as appropriate, also be considered in assigning relative priorities to substances for testing and other regulatory actions.

*Comment 10:* EPA should not require a designation of those chemical substances that are site-limited. This information may be confidential and any use of such a substance for commercial purposes outside the manufacturing site is not necessarily a "significant new use" for the purpose of TSCA section 5(a)(1)(B).

*RESPONSE:* Section 710.5(d)(3) will require designation of those chemical substances which are manufactured and processed within a site and are not distributed for a commercial purpose outside the site. The information will be used by EPA and other agencies to identify those chemical substances which may have little exposure to the general environment.

Section 710.7 of these regulations recognizes that the fact that a particular chemical substance is "site limited" may be claimed as confidential. If a claim of confidentiality is asserted it will be handled in accordance with the Agency's business confidentiality regulations, 40 CFR Part 2.

EPA has not decided exactly how it will propose to define "significant new use" for the purposes of notification under section 5(a)(1)(B). The comments which we have received are quite extensive on this point and correctly emphasize the various considerations set forth in section 5(a)(2). EPA intends to take into account all these considerations prior to issuing a proposed rule under section 5(a)(2).

*Comment 11:* Compilation of production volume and site data will be a time-consuming and expensive procedure since many companies will have to consult production batch sheets and inventories. This burden is greatly increased by requiring the reporting of isolatable intermediates.

*Response:* In preparing the final regulations, EPA has attempted to reduce the burden of reporting to industry while obtaining important information. As discussed in response to comment 6, these regulations would require reporting in fairly broad ranges of the production of chemical substances. Further, as discussed in response to comment 67, EPA has revised its definition of "intermediate" to exclude "isolatable intermediates", or those which "could be isolated," but are not. These amendments should greatly reduce the potential reporting burden to industry. Moreover, the burdens of compiling the production and site information required by these regulations has been considered in establishing the definition of "small manufacturer" under these regula-

tions. As discussed in greater detail in response to comment 24, small manufacturers are not required to submit this information.

*Comment 12:* Certain industries may find it more convenient to report their chemicals in units other than pounds. Cubic feet for gas, and barrels for petroleum products are two examples. Further, manufacturers should be able to report in metric units.

*Response:* In order to simplify reporting and to enable EPA to process the information in a timely fashion, it is very important that manufacturers report production volumes according to the ranges established by § 710.5(d)(4). EPA expects manufacturers who normally deal in other units of measurement to be able to convert to the specified ranges. The table of ranges is provided in both pounds and kilograms to facilitate reporting by persons using the metric system. In instances where manufacturers cannot determine the actual weight of a chemical substance, a best estimate should be made.

#### WHICH PERSONS ARE SUBJECT TO THESE REGULATIONS

##### Manufacturers

*Comment 13:* EPA will lose valuable information by not requiring all chemical manufacturers to report for the inventory. There are many chemical manufacturers outside of SIC groups 28 and 2911 and EPA will not be able to locate these potential sources of hazardous chemicals. The Agency does not have the discretion to exempt some chemical manufacturers from the reporting obligation.

*Response:* The Administrator interprets section 8(a) of the statute as giving EPA broad discretion to determine the manufacturers who shall be subject to any reporting rule.

By directing these reporting requirements to manufacturers substantially engaged in producing chemical products of the types described under SIC 28 or 2911 the Agency is focusing on that segment of the industry which is of primary concern under TSCA. By narrowing the population of manufacturers required to respond from a possible 225,000 establishments who may be engaged in processing chemical substances to approximately 8,400 establishments engaged in manufacturing chemical substances, EPA will dramatically reduce potential duplication of reporting and still create a data base which is comprehensive with respect to principal chemical manufacturers. EPA expects the initial inventory to contain over 95% of the chemical substances manufactured and processed for a commercial purpose in the United States.

In response to this comment, however, in order to increase the reliability of the data base which the Agency will generate, EPA has expanded the category of manufacturers who must report, in two respects. First, § 710.3(a)(1)(i)(B) requires manufacturers who have produced one million or more pounds of a reportable chemical substance(s) at a plant site to report concerning all chemical substances manufactured at that site during 1977. This criterion applies whether or not the manufacturing establishment would be included in SIC Code 28 or 2911. Second § 710.3(a)(1)(ii) requires all manufacturers to report concerning any chemical substance that they manufactured at one plant site in quantities equal to or greater than 100,000 pounds during calendar year 1977.

The Agency, accordingly, will receive reporting on all the chemical substances manufactured at plants included in the chemical and allied products sector of the industry and at the plants of the largest manufacturers in the other sectors. In addition, the data base will include at least all chemical sub-

stances produced in quantities equal to or greater than 100,000 pounds annually at any plant site.

**Comment 14:** Since any manufacturer whose chemical substance is not included in the initial inventory will be required to comply with the premanufacture notification requirements of section 5(a)(1)(A), manufacturers outside SIC groups 28 and 2911 will still be forced to report their chemicals to ensure that they are included on the inventory. Thus EPA's efforts to reduce duplicative reporting will not be successful.

**Response:** The Administrator believes that these regulations will reduce duplicative reporting. Those manufacturers who are not required by § 710.3(a)(1) or (2) to report chemical substances have several options for ensuring the chemical substances they manufacture are included on the inventory. First, they can report individually. Second, these manufacturers can rely on their knowledge that another manufacturer is reporting the chemical substance. Or, third, as provided in § 710.5(f), they can ensure that the chemical substances are reported by a trade association or other group. Thus, the inventory reporting burden on these persons will be minimized and the number of reports submitted to the Agency will be greatly reduced.

**Comment 15:** EPA should clarify by notice in the FEDERAL REGISTER or by direct mailing, exactly who is included in SIC groups 28 and 2911.

**Response:** The Agency intends by direct mail to notify those persons included on the Dun and Bradstreet list of SIC Code 28 or 2911 manufacturers, as well as others who are included on EPA's mailing list, concerning these reporting regulations. Moreover, EPA has decided for administrative and legal reasons not to rely on the designations of SIC groups that the Bureau of Census assigns to all manufacturers. Instead, § 710.3(a)(1) of these regulations sets forth independent criteria for reporting for these regulations. Manufacturers should be able to determine for themselves whether the reporting requirements are applicable to them. The proposed criteria should encompass at least those manufacturers in SIC groups 28 and 2911, as designated by the Bureau of Census. Any manufacturer meeting the criteria of § 710.3(a)(1) is subject to these regulations regardless of whether he has been assigned to SIC group 28 or 2911 by the Bureau of Census and whether he receives a letter from this Agency.

**Comment 16:** Trade associations should let non-member firms add to any list of manufactured chemicals.

**Response:** In allowing trade associations to report, the regulations do not stipulate that the persons for whom the trade associations may report are actual members of that association. Section 710.5(f) of these regulations only requires that for every chemical substance reported by a trade association at least one manufacturer, importer, or processor must have certified to that trade association, and be able to document to EPA, that the chemical substance was manufactured, imported, or processed in accordance with these regulations.

**Comment 17:** A company which contracts with another company to manufacture a chemical substance for a commercial purpose should be allowed to report that chemical substance for the inventory.

**Response:** The Administrator agrees with this comment. EPA recognizes that there are companies who contract with other companies to manufacture chemical substances for commercial purposes. The company who actually manufactures the substance is, of course, responsible for reporting any chemical substance manufactured during calendar year 1977, in accordance with § 710.3(a)(1). In addition, the manufacturer may report for

the inventory under § 710.3(a)(3). The company who has contracted for manufacture of the chemical substance may also report for the initial inventory, if he has reason to believe that the manufacturer has no intention of reporting the substance. For example, the manufacturer may no longer be in business or may not have manufactured the substance since January 1, 1977, and does not intend to continue manufacturing the chemical substance. If the contractor reports for the inventory he must be able to certify that the chemical substance was manufactured since January 1, 1975, and provide the address of the manufacturing site.

#### Importer

**Comment 18:** Importers and foreign suppliers should be permitted to appoint a mutually agreeable agent to report for the inventory. It is unfair to hold small importers liable for reporting the chemicals manufactured by a large international corporation.

**Response:** Section 710.5(e) of these regulations provides that an importer required to report chemical substances may authorize a foreign manufacturer, or an agent of a foreign manufacturer, to report on the importer's behalf. Because the jurisdiction of TSCA reaches the importer and not the foreign manufacturer, EPA must hold the importer liable. An importer is free, however, to take whatever legal measures are necessary in contracts with the foreign supplier to protect himself from penalties. Whatever conditions the importer and reporting agent agree to, however, are outside the purview of these regulations.

In addition, the reporting instructions referred to in § 710.5(b), "Reporting for the TSCA Inventory," will provide that importers may report certain information directly to EPA and request a foreign manufacturer or his agent to supply other information. Thus, an importer could arrange that he would send directly to EPA the trade name of the imported chemical substance and the amount imported, and that a foreign manufacturer or his agent would submit the specific chemical identity of the trade name substance. The Agency expects such arrangements to be useful in the event some information is a confidential trade secret.

**Comment 19:** Standard Industrial Classification (SIC) codes should be used to determine which importers are required to report. EPA should insure that importers are not required to report under § 710.3(a)(1) and should clarify the "site" for importers for the purposes of these regulations.

**Response:** The Administrator agrees in part with this comment. EPA has revised the final regulations to require reporting by importers concerning all chemical substances imported if (1) thirty percent or more of the weight of the products imported consists of products of the types described under SIC 28 or 2911, or (2) the total pounds of reportable chemical substances imported equals one million or more pounds. In addition, importers must report any chemical substance imported during calendar year 1977 in quantities equal to or greater than 100,000 pounds. These requirements parallel those under § 710.3(a)(1) for domestic manufacturers. An importer, however, is not required to report under § 710.3(a)(1); he is required to report under § 710.3(a)(2).

As defined in § 710.2(w), the business address of an importer will be considered his site for the purposes of these regulations. Importers need not specify the port of entry for importation of a chemical substance.

**Comment 20:** If EPA allows mixtures which contain substances not on the inventory to be imported, foreign competitors will have an unfair advantage. EPA should require

premanufacture notification of new chemical substances imported as parts of mixtures.

**Response:** The Administrator agrees with this comment. On October 3, 1977, EPA published in the FEDERAL REGISTER a supplemental notice (42 FR 53804) addressing the applicability of these regulations and premanufacture notification requirements to importers of chemical substances as part of mixtures. Since an importer of a mixture is also importing the component chemical substance in the mixture, such an importer would be subject to the premanufacture notification requirements with respect to all new chemical substances. Accordingly, although importers of chemical substances as part of mixtures are not required to report for compilation of the inventory, they should ensure that the chemical substances they import are included on the inventory. As provided in §§ 710.3(a)(3) and 710.3(b), they may report either during the reporting period for the initial inventory or the reporting period for the revised inventory. And, as provided in § 710.5(f), they may report through a trade association or other agent. The premanufacture notification requirements of section 5(a)(1)(A) will not be applied to importers of chemical substances as part of mixtures until 30 days after publication of the revised inventory. At that time, no person will be permitted to import any mixture containing a "new chemical substance" except in accordance with TSCA section 5. Please refer to the October 3, 1977 notice for a discussion of the legal and policy considerations supporting this decision.

**Comment 21:** Importers of chemical substances as part of articles should not be required to report for the inventory and should not be subject to premanufacture notification.

**Response:** The Administrator agrees that importers of chemical substances as part of articles should not be required to report for the inventory, and is reviewing whether any importers of articles should be subject to premanufacture notification requirements. Sections 710.3(a)(3) and 710.3(b) provide, however, that importers of a chemical substance as part of an article may report for the initial and revised inventory.

The October 3, 1977 supplemental notice (42 FR 53804) in the FEDERAL REGISTER discussed the applicability of these regulations and premanufacture notification requirements to importers of chemical substances as part of articles. Persons who import articles also "import" the component chemical substances. Thus, as discussed in response to comment 20, the importer could be subject to the premanufacture notification requirements with respect to all new chemical substances comprising the article. However, for reasons discussed in greater detail in the October 3, 1977 notice, the Administrator does not presently intend the premanufacture notification requirements of section 5(a)(1)(A) to be applied to the importation of all articles that contain a new chemical substance. As discussed in response to comment 22, EPA will carefully consider the economic and international ramifications of any premanufacture notification requirements that may be applied to chemical substances imported as part of articles. In the interim, EPA will not consider persons who import chemical substances as part of articles or who process or use such articles to be in violation of section 5(a)(1)(A). If upon re-evaluation, the Administrator determines that these requirements should be applied to importers of chemical substances imported as parts of some or all articles, or to importers of selected chemical substances imported as parts of articles, a proposed notice will be published for further public comment. Such change in policy would be final-

ized before publication of the initial inventory so that any affected parties may report during the reporting period for the revised inventory.

Chemical substances or mixtures which are imported within articles, such as in drums, barrels, or other containers used for purposes of transportation or containment, are considered to be chemical substances imported in bulk and are subject to these reporting requirements. Chemical substances or mixtures will be considered to be imported as a part of an article, if the substance or mixture is not intended to be removed from that article and has no end use or commercial purposes separate from the article of which it is a part. Importers may report these chemical substances but are not required to do so. For example, transformer fluids in transformers, lighter fluids in cigarette lighters, and crankcase oil in automobiles are not intended to be removed from the articles of which they are a part and have no commercial purpose separate from these articles. Accordingly, these chemical substances need not be reported. These same chemical substances, however, if imported in drums, cans, or other containers, must be reported as required by these regulations.

The Agency will exercise its authority to regulate the import of chemical substances which are part of articles (as well as imported in bulk and in mixtures) under section 6 or other authorities of the Act, as necessary to protect against unreasonable risks of injury to health and the environment. This might, for example, include prohibiting, limiting, or, in other ways, restricting the import of such chemical substances.

**Comment 22:** Importers of chemical substances as part of an article have an unfair competitive advantage over domestic manufacturers because they can introduce new chemical substances into domestic markets without complying with premanufacture notification requirements. This policy should be changed so that substances which are manufactured domestically at a site solely to be included in an article would not be considered commercial substances per se. Thus they would not be reported for the inventory and would not be subject to premanufacture notification.

**Response:** The Administrator disagrees with this comment. EPA recognizes that the reporting requirements are not identical for importers and domestic manufacturers of chemical substances as part of an article, but EPA has tried to equalize the burdens of complying with these regulations, as directed by the Act. With respect to the requirements for premanufacture notification, EPA will assess the impact of those requirements over the next several months as they are developed.

Under § 710.4(d) of these regulations some chemical substances manufactured as part of an article which have no commercial purpose separate from the article of which they are a part, are excluded from the inventory and premanufacture notification requirements. To exclude from the inventory other chemical substances manufactured for a commercial purpose which are subsequently incorporated in an article would create an unacceptable loophole and not fulfill the purposes of the TSCA inventory. The domestic manufacturer of a chemical substance who also manufactures an article is only required to report the chemical substance(s) he actually manufactures. EPA does not believe that this is an unreasonable burden. If under subsequent regulations the Agency imposes certain requirements on domestic manufacturers of chemical substances which are incorporated as parts of articles, in general the Agency will impose the same require-

ments on importers of those chemical substances.

**Comment 23:** In developing premanufacture requirements under section 5, EPA should take into account foreign manufacturers whose application for a patent for a new chemical substance with a foreign government may be jeopardized by premanufacture notification under TSCA.

**Response:** If a foreign government will not award a patent for a chemical substance whose identity has been disclosed, even to another government under a provision such as the premanufacture notification requirements of TSCA, persons should take this into account and apply for the patent prior to the importation of the chemical substance into the United States.

#### Definition of Small Manufacturer or Importer

**Comment 24:** The definition of "small manufacturer or importer" proposed by EPA is unduly restrictive and ought to be revised.

**Response:** The Administrator agrees with this comment. The definition of the term "small manufacturer or importer" at § 710.2 (x) has been revised to mean a "manufacturer or importer whose total annual sales is less than \$5 million, based upon the manufacturer's or importer's latest complete fiscal year as of January 1, 1978, except that no manufacturer or importer is a 'small manufacturer or importer' with respect to any chemical substance which such person manufactured or imported in quantities greater than 100,000 pounds during calendar year 1977."

This definition is different in several respects from the definition of "small manufacturer or importer" which was proposed on August 2, 1977. In the first place, EPA has deleted the criterion based on the number of plant sites. It had been proposed that a manufacturer would be a small manufacturer if he had only one plant site. The Administrator has determined that for the purposes of these regulations, such a criterion would have little meaning. The one plant site criterion had little relation to burden on the small manufacturer. It also provided very little benefit to EPA because very few manufacturers who meet the other criteria will have more than one plant site.

In the second place, whereas the August proposal would have defined as a "small manufacturer or importer" a person with total sales of less than \$100,000, these final regulations consider a "small manufacturer or importer" a person who, in part, has total annual sales of less than \$5 million, based on the manufacturers' or importers' latest fiscal year as of January 1, 1978. The Agency received extensive comments that the \$100,000 figure was unreasonably low, and has agreed that it should be substantially increased.

And, in the third place, these regulations provide that no person is a "small manufacturer or importer" with respect to any chemical substance produced in quantities greater than 100,000 pounds annually. The August proposal had provided that a person would be a small manufacturer if he had no more than 2,000 pounds annual production of a chemical substance. The Agency has established this criterion for the definition of the term "small manufacturer or importer" based on its need for information on chemicals produced in substantial quantities.

It is important to emphasize that in accordance with section 8(a)(3) of TSCA, small manufacturers and importers are not exempt from reporting information necessary for compilation of the inventory. Accordingly, under these regulations, small manufacturers and importers who are required to report (§ 710.3(a) (1) and (2)) must report

at least (1) the identities of the chemical substances, and (2) whether they manufacture, process, or import the substance. Reporting of the chemical identities is necessary to publish the list required under section 8(b). In order to enforce these inventory reporting regulations, manufacturers, and importers must indicate whether they do manufacture or import the substance.

Under these regulations "small manufacturers" are also required to report whether the chemical substance is manufactured and processed only within one site and not distributed outside that site. The Administrator has determined that this is very important for utility of the inventory and that the burden of reporting this additional information by manufacturers is negligible. Specifically, EPA may want to use this information, i.e., which chemical substances are now "site-limited", for purposes of requiring notification under section 5(a)(1)(B) prior to distribution of such substances outside the manufacturing site.

Small manufacturers and importers are exempt from reporting the production volume and site information that will be required by these regulations. As is discussed in response to comments 1 through 12, this information is being required pursuant to the general reporting authority of section 8(a) to obtain sufficient information to implement the provisions of TSCA. In defining "small manufacturer or importer" EPA has attempted to balance the burdens to manufacturers and importers of submitting this information against the value of that information to the Agency.

The Administrator has determined that requiring production and site information from all manufacturers and importers other than "small manufacturers and importers" as defined in these regulations, will not present an unreasonable burden. For those firms with approximately \$5 million in sales, the costs of reporting will range from about 0.6 percent of annual profits (for reporting for the inventory alone) to about 1.2 percent (for also reporting product volume and identity of substances manufactured by site). These figures assume a 6 percent profit rate. For example, a firm with \$5 million in sales and \$300,000 in profits (6 percent) would have to spend about \$3,500 (1.2 percent of \$300,000) to comply with these regulations. The above costs would decrease as the size of the firm increases.

The firms generally most impacted are those with the largest number of chemicals to report. Those firms with less than \$5 million in sales must report production volume by site for chemicals manufactured in quantities in excess of 100,000 pounds. The costs to these firms will fall between 0.6 and 1.2 percent of profits, or between the costs of reporting for the inventory alone and the costs of reporting all required information.

In analyzing the costs of reporting, EPA examined the costs to those required to report under section 710.3. The bulk of respondents would fall in SIC group 28, Chemicals and Allied Products, or SIC 2911, Petroleum Refining. The remaining respondents are those who are not classified as SIC 28 or 2911 firms but who have at least one site from which thirty percent or more of products distributed are of the type described by SIC 28 or 2911, or who either manufacture a total of one million or more pounds of reportable chemical substances or manufacture one or more chemical substance in quantities of 100,000 pounds or greater. The costs per chemical of reporting for these additional firms would be similar to the costs estimated for the SIC 28 and 2911 firms. However, the costs as a percentage of sales would be smaller because chemical sales are a relatively smaller portion of their total sales.

In estimating the number of firms required to report by these rules, EPA started with the firms classified as primarily producers of SIC 28 and 2911 products. This number was then reduced to account for those firms within SIC 28 and 2911 who are not manufacturers (i.e., processors) and those whose primary products are not covered by TSCA (e.g., SIC 283, Drugs and SIC 2879, Pesticides). Firms whose major products are not in SIC 28 or 2911 but which had significant chemical manufacturing activities were also examined and included in the analysis. The total number of firms expected to be required to report is estimated to be approximately 5400.

This definition of small manufacturer will exempt approximately 78 percent of the firms required to report from complete reporting of production and site information. Though the number of firms defined as small is significant, they account for less than 5 percent of the sales and 6 percent of employment.

EPA has consulted with the Small Business Administration (SBA) in developing this definition of "small manufacturer or importer." The SBA suggested that EPA define as a "small manufacturer or importer" a company with 100 employees or less. Such a definition would exempt a slightly larger percent of firms; it would be equivalent to exempting companies whose total annual sales are approximately \$6.8 million. These final rules substantially reduce the burden of reporting by requiring reporting only for intermediates which are actually isolated (see comment 67) and by requiring reporting of production volumes in broad ranges (see comment 6). Based on these changes, EPA believes that the definition of "small manufacturer or importer" in these regulations is adequate to prevent unreasonable burdens on chemical manufacturers. The SBA concurs.

Further analysis of the costs associated with this definition of "small manufacturer" is contained in the report, "Analysis of Options for Definition of Small Business and Estimated Cost of the Initial Section 8(a) Reporting Requirements", prepared by Arthur D. Little, Inc. and included in the rulemaking record.

**Comment 25:** Several commenters suggested that EPA should define "small manufacturer or importer" in terms of production volume and total annual sales; other commenters suggested that the term should be defined in terms of manufacturing sites, number of employees, assets, or value of sales per chemical.

**Response:** The Administrator considered the utility of each of these parameters and, as is discussed in response to comment 24, has decided to rely on total annual sales and production volume.

The total annual sales of a manufacturer or importer are generally known and, therefore, use of this criterion would require no additional calculations. In addition, the value of sales gives a good indication of the ability of the company to bear the reporting burden. Generally the larger the sales, the larger the staff employed by the firm, and the more resources the company will have available to report to the Agency.

Production volume gives a good indication of the potential for human and environmental exposure. Accordingly, these regulations use this criterion in conjunction with the sales criterion. However, a manufacturer or importer with total annual sales of less than \$5 million dollars only must report production volumes for those chemical substances produced in quantities greater than 100,000 pounds. Information on chemicals produced in such quantities has greater value to the Agency.

As discussed in response to comment 24, the Administrator had determined that a cri-

terion on number of manufacturing sites would have little meaning for the purposes of this regulation. It has no relation to cost or burden on a company and the additional information gained by EPA by including this criterion would be minimal since very few firms that satisfy the other criteria of the definition would have more than one plant site.

The number of employees of a manufacturer or importer may be useful a parameter for determining the burdens of a reporting requirement. However, it is not as good a measure as sales of the ability to bear the burden of reporting. This is particularly true since there are significant variations in dollar sales per employee in various segments of the chemical industry reflecting a substantial difference in the abilities of various firms to bear the burden of reporting. Over the entire industry, annual sales per employee is about \$68,000, varying from \$45,000 in SIC 2816, Inorganic Pigments to over \$225,000 in SIC 2911, Petroleum Refining.

Criteria based on assets or value of sales per chemical are also not included in these regulations. The value of assets would provide an indication of the size of a firm. However, the components of total assets are complex and the information is not generally available to the public. Further, assets may not bear any relationship to a company's ability to absorb these reporting costs. Value of sales per chemical produced might provide a good measure of a company's ability to bear reporting costs; however, this criterion would require a company to make a determination as to whether it was a "small manufacturer or importer" with respect to every chemical manufactured. This would be an unnecessary burden.

**Comment 26:** Including a volume of production limit as part of the definition of "small manufacturer or importer" is consistent with the Act and will give EPA at least a rough estimate of the quantities of chemicals produced.

**Response:** As discussed in comment 24, in determining an appropriate definition of "small manufacturer or importer," EPA considered the value of and need for this information with respect to the costs to manufacturers and importers of submitting the information. Production data are to be used primarily in decisions concerning prioritization of Agency actions and allocations of Agency resources. Because of this, the Agency's need for the information grows as production volume increases, thus justifying an increased burden to small businesses who produce large quantities of chemical substances. EPA is requiring reporting of production volumes in excess of 100,000 pounds from all companies. Under these final regulations, reporting production volumes should not be burdensome, especially for those substances manufactured in substantial quantities.

**Comment 27:** EPA should define the term "small manufacturer" without respect to whether a manufacturer is owned or controlled by another company. A manufacturer who meets the basic criterion should be considered a "small manufacturer," even if the manufacturer's company is owned or controlled by another company.

**Response:** The Administrator disagrees with this comment. The legislative history of TSCA makes it clear that in considering what manufacturers and processors qualify as "small manufacturers and processors," the Administrator must consider whether the company is owned or controlled by another company and apply the factors for determining "small manufacturers or processors" to both companies. H. Rep. No. 94-1341, 94th Cong., 2nd Sess. 5 (1976).

## Processors

**Comment 28:** EPA does not have the discretion to prevent processors of chemical substances (including manufacturers of a mixture or article containing the chemical substance) from reporting for the initial inventory.

**Response:** EPA interprets section 8(a) of the statute as providing broad discretion to determine which persons shall be subject to any reporting rule. Section 710.3(c) provides that the processors are not subject to the initial inventory. They may report chemical substances not included on the initial inventory during the reporting period for the revised inventory.

These regulations provide that persons who will be subject to the premanufacture notification requirements of section 5(a)(1)(A) of the Act are subject to the initial inventory. The requirements of section 5(a)(1)(A) only apply to manufacturers and importers of chemical substances; processors of chemical substances are not required to give premanufacture notification on new chemical substances. Therefore, processors are not subject to the initial inventory.

If processors were subject to the initial inventory, the Agency expects that the number of respondents would increase ten-fold. Moreover, the Agency expects the list of chemical substances reported by manufacturers and importers to contain over 95 percent of the chemical substances which are manufactured or processed for a commercial purpose in the United States. Accordingly, by making processors and users of chemical substances subject to only the revised inventory, the Agency will avoid duplicative reporting and substantial delays in publication of the inventory. The Agency will not process any reports submitted for the initial inventory by processors or users of chemical substances.

It is a prohibited act under section 15(2) of TSCA for a person to use for a commercial purpose a chemical substance which he had reason to know was manufactured in violation of section 5. The Agency has announced, however, that section 15(2) with respect to section 5(a)(1)(A) will not be applied to persons who process or use a chemical substance for a commercial purpose until publication of the revised inventory. Therefore, by reporting during the reporting period for the revised inventory, processors of chemical substances will be able to protect themselves from prosecution under the statute.

## CHEMICAL SUBSTANCES MANUFACTURED OR PROCESSED FOR A COMMERCIAL PURPOSE

**Comment 29:** The definition of the term "manufacture for a commercial purpose," should be modified to exclude the manufacture of a chemical substance in small quantities for research and development.

**Response:** The Administrator disagrees with this comment. Chemical substances which are manufactured for research and development are "manufactured for commercial purposes" within the meaning of TSCA and are appropriately included under this definition. However, if these substances are produced solely in small quantities for research and development they are specifically excluded from the inventory under section 8(b), and are exempt from the premanufacture notification requirements of section 5(a) by section 5(h)(3) of the Act.

**Comment 30:** Commercial biological preparations such as yeasts, bacteria, and fungi should not be considered "chemical substances" under TSCA.

**Response:** The Administrator disagrees with this comment. The term chemical substance is defined to mean "any organic or inorganic substance of a particular molecu-

lar identity including any combination \* \* \* occurring in nature." This definition does not exclude life forms which may be manufactured for commercial purposes and nothing in the legislative history would suggest otherwise.

# EXCLUSIONS TO THE DEFINITION OF CHEMICAL SUBSTANCES

## Mixtures

**Comment 31:** EPA should clarify that manufacturers, not processors, have the responsibility for reporting the component chemical substances of a mixture.

**Response:** EPA believes that these regulations clarify that only manufacturers of chemical substances must report for the initial inventory. In fact, processors are not subject to the initial inventory. Processors, including manufacturers of mixtures, may report for the "revised" inventory.

**Comment 32:** Multi-nutrient "mixed fertilizers" that could have been prepared by physically blending dry products such as urea, superphosphate, and potash, should be considered mixtures, regardless of whether they are produced by physically mixing or by a method that involves a chemical reaction, such as by combining liquid ammonium phosphate and granulating with potash.

**Response:** The Administrator agrees with this comment and will consider multinutrient "mixed fertilizers" as mixtures of the ingredients being mixed.

**Comment 33:** Manufacturers of alloys including steel, glasses, ceramics, enamels, Portland cement, and similar combinations of chemical substances should not be required to report for the inventory.

**Response:** The Administrator agrees with this comment. Alloys, inorganic glasses, ceramics, frits, and cements, including Portland cement, are mixtures under TSCA; manufacturers of these products are not required to report them. However, as stated in a note at § 710.4(c), the exclusion of these products applies only to the mixture and not to the chemical substances of which the mixture is comprised. Thus, the metals in the case of alloys, or oxides in the case of glasses and ceramics, and any additives or components other than impurities, should be included on the inventory. The manufacturers of the metals, oxides, and additives would be responsible for reporting them.

**Comment 34:** "Hydrates" and "hydrated ions" should be considered "mixtures."

**Response:** The Administrator agrees with this comment and has defined the term "mixture" to include "hydrates." Hydrated forms of chemical substances are accordingly exempt from the inventory. The anhydrous chemical substances, however, should be included. Thus the manufacturer of hydrated copper sulfate,  $\text{CuSO}_4 \cdot (\text{H}_2\text{O})_x$ , would report that anhydrous form,  $\text{CuSO}_4$ , for the inventory. As clarified in the preamble to the March 9 regulations, this provision does not apply to the product of discrete chemical reactions in which either water or a solvent is a reactant, e.g., water reacting with an ester to form an acid and an alcohol. Similarly, metal hydroxides formed by the reactions of metal oxides with water are not considered to be hydrates.

**Comment 35:** If a person combines two or more chemical substances to produce a "mixture," the person should be considered a "manufacturer of the mixture," not a "processor of a chemical substance."

**Response:** The Administrator disagrees with this comment. A person who combines two chemical substances to produce a mixture, the person should be considered a "processor of the mixture" or a "processor of the chemical substance." For the purposes of these regulations, regardless of how such

a person is characterized, he may only report during the reporting period for the revised inventory.

The Agency recognizes that the Congress in section 8(a) established a different standard for requiring reporting and retention of information on mixtures than on chemical substances. EPA does not intend to require reporting on mixtures from either their manufacturers or processors when information concerning the chemical substances which comprise the mixture is adequate for the Agency's purposes.

**Comment 36:** The definition of the term "mixture" should be expanded to include (1) incidental reaction products, (2) some chemical substances, (3) chemical substances which are the result of a chemical reaction that occurs upon use of certain chemical substances, such as curable plastic or rubber molding compounds, or other substances which are formed during the manufacture of an article, and (4) chemical substances which occur as the result of a chemical reaction when specified substances including, for example, a stabilizer, colorant, or antioxidant, function as intended, or when a chemical substance which is solely intended to impart specific physico-chemical characteristics, functions as intended.

**Response:** The Administrator disagrees that the substances encompassed within this comment are "mixtures" within the meaning of TSCA. EPA believes that each of the reaction products is a "chemical substance" for the purposes of TSCA and that the chemical substance is manufactured or processed for a commercial purpose within the meaning of section 8 of the Act. However, in keeping with the legislative history of the Act, § 710.4(d) excludes all these substances from the inventory because they are not manufactured for distribution in commerce as chemical substances *per se* and have no commercial purposes separate from the mixture or article of which they may be a part. In addition, they are not subject to the premanufacture notification requirements of section 5. The Administrator may in the future impose a section 8(a) reporting rule as to these substances. In addition, the provisions of sections 8(c), 8(d) and 8(e) are applicable to these substances.

The term "mixture" under TSCA has a meaning which is different from its usual meaning in some respects. Many compositions commonly considered to be mixtures are "chemical substances" rather than "mixtures" for purposes of these regulations.

A combination of two or more chemical substances is itself a "chemical substance" for purposes of these regulations unless it falls within the specific definition of the term "mixture." In general, a combination of two or more chemical substances is a "mixture" if they have been combined by actually mixing them together.

If, however, the combination occurs in nature, it is a "chemical substance" and is not a "mixture." If, further, the combination is prepared by a chemical reaction, it is a "chemical substance" and not a "mixture," unless the combination could actually have been manufactured for commercial purposes at this time without a chemical reaction e.g., by mixing its separate components with each other.

**Note.**—Hydrates and hydrated ions are treated separately, and are discussed in comment 34.

## Pesticides and Foods, Food Additives, Drugs, Cosmetics and Devices

**Comment 37:** Various commenters stated that a substance should be excluded from TSCA if it is intended for use solely as a pesticide, food, food additive, drug, cosmetic, or device.

**Response:** The Administrator agrees with these comments. Pesticides are regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 USC 136 et seq. Foods, food additives, drugs, cosmetics, and devices are regulated under the Federal Food, Drug and Cosmetic Act (FFDCA), 21 USC 321 et seq. If the manufacturing, processing, distribution, or use of a substance is regulated under either FIFRA or FFDCA, the substance would not be subject to regulation under TSCA insofar as it is actually manufactured, processed or distributed in commerce for use as a pesticide, food, food additive, drug, cosmetic or device. If a substance has multiple uses only some of which are regulated under FIFRA or FFDCA, the manufacture, processing, distribution, and use of the substance for the remaining uses would come within the jurisdiction of TSCA. In cases where a substance is manufactured, processed, or distributed for undifferentiated uses, the substance will be presumed to be subject to TSCA for the purposes of these regulations. EPA recognizes that the interrelationship of TSCA, FIFRA, and FFDCA is complex and that jurisdictional issues need further exploration in light of the various types of regulatory situations that may arise and the Congressional intent of avoiding both dual jurisdiction and regulatory gaps. EPA believes that an appropriate resolution has been made in this particular instance.

**Comment 38:** A substance should be considered a pesticide at the time that an application for an experimental use permit or an application for registration is submitted.

**Response:** The Administrator agrees with this comment. If a manufacturer, processor, or distributor of a substance expects to receive benefit in pest control from its use, it would be considered a pesticide within the meaning of FIFRA. Submission of an application for an experimental use permit (FIFRA) section 5, 40 CFR Part 172) or an application for registration (FIFRA) section 3, 40 CFR Part 162) will be evidence that the substance is a "pesticide" within the meaning of FIFRA. Prior to this stage, the substance will be presumed to be a chemical substance within the meaning of TSCA. Therefore, any particular substance will first be subject to the provisions of TSCA and then, the provisions of FIFRA.

Implementation of this approach will not pose an unreasonable burden on registrants of pesticide products. The substance will be considered a "chemical substance" under TSCA at the research and development stage. Assuming that the substance is only produced in small quantities for research and development (as defined in these rules), under the exemption of section 5(h)(3), the TSCA premanufacture notification requirements would not apply. The Administrator could require that all persons engaged in experimentation, research or analysis of the substance be notified of any risk to health which may be associated with the substance. This is entirely in keeping with the purposes of TSCA.

In addition, the Administrator could take regulatory action on the substance under TSCA sections 4, 6 or 7, and could require reporting under section 8(a)(1)(B). The Agency recognizes the importance of research and development and does not intend to impede such innovation unnecessarily. Chemicals in the research and development stage are generally handled by technically qualified persons and only in small quantities. Accordingly, although the Agency may take regulatory action (including labelling and disposal requirements) in order to regulate inadvertent mishandling of research chemicals by an untrained person and inadvertent exposure to the environment of the research chemical, submission of test data and extensive regulation of the uses of the substance

would normally be limited to situations involving significant exposure. In the case of a research chemical which becomes a pesticide, these latter areas of concern would be addressed under FIFRA.

**Comment 39:** Various commenters maintained that raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide should be considered "pesticides" and excluded from regulation under TSCA. Other commenters argued that raw materials and intermediates produced or used in the manufacture of a pesticide are not "pesticides," are not covered under FIFRA, and should be regulated under TSCA.

**Response:** The Administrator agrees that raw materials, intermediates and inert ingredients produced or used in the manufacture of a pesticide are substances or mixtures which can be regulated under TSCA.

In order to be considered a pesticide, a substance must be intended for use as a pesticide. Raw materials, intermediates, and inert ingredients produced or used in the manufacture of a pesticide are not themselves regulated under FIFRA (unless they happen to be pesticides themselves) and, therefore, are subject to TSCA. The pesticide regulations at 40 CFR 162.4 are consistent with this view. A manufacturing use product is considered a pesticide, (40 CFR 162.4(b)(3)); an intermediate substance intended for the production of a pesticide product by chemical reaction with other substances is not considered a pesticide, (40 CFR 162.4(c)(6)).

The legislative history of TSCA also supports this view. TSCA was enacted to provide protection from harmful chemicals where legal authority was previously inadequate, cumbersome or inefficient. Congress intended to avoid the possibility that the risks from a chemical would not be subject to regulation. S. Rep. No. 94-698, 94th Cong., 2d Sess. 5 (1976). H. Rep. No. 94-1341, 94th Cong., 2d Sess. 6 (1976). In addition, Senator Allen of the Senate Committee on Agriculture and Forestry in attempting to conform the language of TSCA to that of FIFRA specifically addressed the interface between FIFRA and TSCA stating: "... any chemical or toxic substance would first be subject to the provisions of (TSCA) and yet when it becomes a component of a pesticide, it would be subject to FIFRA. In many instances the manufacturer and registrant of the component is also the manufacturer and registrant of the pesticide." Committee on Interstate and Foreign Commerce, 94th Cong., 2d Sess., Legislative History of the Toxic Substances Control Act 232 (1976). A raw material, intermediate, or inert ingredient which is not itself a pesticide would, accordingly, be a chemical substance within the jurisdiction of TSCA; it would come within the jurisdiction of FIFRA when it becomes a component of a pesticide product.

The manufacturer, processor, or distributor of the chemical substance who does not also manufacture, process or distribute a pesticide product will not be subject to the dual jurisdiction of TSCA and FIFRA. That person will only be subject to TSCA. The manufacturer, processor, and distributor of the raw material, intermediate, or inert ingredient who also manufactures the pesticide product will be subject to the jurisdiction of both acts. TSCA and its legislative history contemplates this, and EPA has no discretion to reach a different result since a raw material, intermediate, or inert ingredient (which is not itself a pesticide) cannot be regulated under FIFRA until it becomes a component of a pesticide product. As a matter of policy, however, EPA does not intend to impose duplicative requirements on these substances.

**Comment 40:** A substance should be considered a food, food additive, drug, cosmetic or device at the time that the Food and Drug Administration (FDA) regulates the substance.

**Response:** The Administrator agrees with this comment. As soon as the FDA regulates a product, its manufacture, processing, or distribution in commerce solely for a FDA regulated use will be excluded from the jurisdiction of TSCA. The FDA gives as examples of such points in time: when an application for exemption for an investigational use of a new drug is submitted (FFDCA 505(a); 21 CFR Part 312); when an application for exemption for investigational use of a new animal drug is submitted (FFDCA 512(a); 21 CFR Part 511); and when an application for exemption for investigational use of a device is submitted (FFDCA 520(g); 21 CFR Part 812, as proposed, 41 FR 35282, August 20, 1976).

**Comment 41:** Intermediates and catalysts intended solely for use in the production of a food, food additive, drug, cosmetic, or device are excluded from regulation under TSCA.

**Response:** The Administrator agrees with this comment. The definitions of the FFDCA provide that chemical substances which are intended for use as a component of a food, food additive, drug, cosmetic, or device are encompassed within the meaning of such terms, respectively. The FDA considers intermediates and catalysts to be such components. Therefore, they are subject to regulation under the FFDCA. Any such substance is excluded from regulation under TSCA insofar as it is actually manufactured, processed or distributed in commerce solely for use in the production of a food, food additive, drug, cosmetic or device.

**Comment 42:** Substances which are approved for use by the Food and Drug Administration as foods or food additives, should be excluded from further regulation under TSCA even when used for commercial (non-food) uses.

**Response:** As discussed in response to comment 37, if a substance has multiple uses only some of which are regulated under the FFDCA, the manufacturing, processing, distribution, and use of the substance for the remaining uses comes within the jurisdiction of TSCA. Under these regulations, that substance should be reported for the inventory.

EPA does not intend to impose duplicative requirements on manufacturers and processors subject to regulation under another Federal authority. Accordingly, EPA will consult with FDA or any other Federal agency, as appropriate, prior to taking regulatory action on substances which are also regulated under other authorities.

#### CHEMICAL SUBSTANCES EXCLUDED FROM THE INVENTORY

##### Small Quantities for Research and Development

**Comment 43:** The exemption for "small quantities for research and development" should include small quantities used for quality control testing and for development of a chemical substance or product.

**Response:** The Administrator agrees, in part, with this comment. Chemicals used for quality control testing and for the development of a product are considered "small quantities for research and development" if they fall within the definition provided in § 710.2(y). Specifically, they must be manufactured or processed in quantities no greater than reasonably necessary for such purposes and, after publication of the revised inventory, they must be used by, or directly under the supervision of, "technically qualified individual(s)," a term defined in § 710.2(aa). Substances can be "small quantities for re-

search and development" even if they are distributed in commerce.

**Comment 44:** Numerical limits should be included in the definition of small quantities for research and development.

**Response:** The Administrator considered establishing upper limits for small quantities for research and development and found that different values might have to be assigned for various groups of substances depending upon their physical/chemical characteristics and intended uses. For example, many plastics and fibers are commonly produced in 100,000 pound quantities during the developmental phase, while additives or minor use substances may be manufactured in a few thousand pounds or less for research and development purposes. After compilation of the inventory, the Agency will consider developing a schedule of quantities to define small quantities for different chemical substances and different purposes.

For these reporting requirements, however, EPA will in large part rely on the qualitative test contained in the definition at § 710.2(y). In response to this comment, as provided in a note to the definition, if a substance is manufactured or imported in quantities of less than one thousand pounds, annually, it will be presumed to be for research and development purposes. If a manufacturer wishes to report for inclusion on the inventory a chemical substance which is manufactured for commercial purposes in quantities of less than one thousand pounds, annually, he must be able to certify that the substance is used for purposes other than for research and development. After the publication of the revised inventory, in order to qualify as a "small quantity for research or development," these quantities must be used by, or directly under the supervision of, a technically qualified individual.

**Comment 45:** The exemption for "small quantities" should not extend to research or analysis of chemical substances for the development of a product. The exemption should apply only to research in a laboratory and not to situations where production workers are exposed.

**Response:** The Administrator disagrees with this comment. The legislative history of the Act makes clear that Congress intended the exemption for "small quantities" to extend to chemical substances in the developmental period and not only to research chemicals in a laboratory. H.R. Rep. No. 94-1341, 94th Cong., 2d Sess. 29-30 (1976). The Congress contemplated that during the research and development phase, a chemical substance would be within the control of technically qualified individuals who would appreciate the risks from exposure to the substance and be able to minimize such risks. The regulations provide that a compound will only qualify for the "small quantities" exemption if it is used by, or directly under the supervision of, technically qualified individual(s). The Agency expects this requirement to provide workers in the development of a product the same protections as workers in the laboratory. In addition, section 5(h)(3) of the Act specifically provides that in order for a substance to be exempted from the requirements of premanufacture notification, all persons handling the chemical substance for the manufacturer or processor must be notified of any risk to health which the manufacturer, processor or the Administrator has reason to believe may be associated with it.

**Comment 46:** The exemption for "small quantities" should not extend to chemical substances distributed in commerce.

**Response:** The Administrator disagrees with this comment. Congress recognized that

a manufacturer may not be able to evaluate fully a potential product in house. So long as the research and evaluation of the substance is conducted by or under the direct supervision of persons technically qualified to analyze and evaluate the physical, chemical, and performance characteristics of the substance, the Congress intended the exemption to apply. H.R. Rep. No. 94-1341, 94th Cong., 2d Sess. 30 (1976).

**Comment 47:** After the effective date of the premanufacture notification requirements, EPA should require all research and development chemicals to be labeled rather than require a "certification of use" statement by a customer upon each sale.

**Response:** The Agency recognizes that it may be unnecessarily burdensome to require customers to certify upon each sale (or even annually) that the chemical substances they purchase are for research and development only. EPA is considering imposing a labeling requirement on all research and development chemicals (such as "For Research And Development Use Only") and requiring distributors of such chemicals to include statements in their catalogs and sales literature detailing the restrictions on use.

**Comment 48:** EPA should clarify the responsibilities under these regulations of persons who manufacture or import chemical substances solely in small quantities for research and development.

**Response:** Chemical substances manufactured, imported, or processed solely in small quantities for research and development as defined at § 710.2(y) are excluded from reporting for the inventory under § 710.4(c)(3). As discussed above, if a person manufactures or imports a chemical substance in quantities of less than one thousand pounds annually, the substance is presumed to be for research and development. In such a case, in order to report the substance a manufacturer or importer must be able to certify that the substance is being used for purposes other than research and development.

With respect to quantities greater than one thousand pounds, manufacturers and importers are not required to obtain certification from their customers concerning the intended use of such chemicals. However, unless a manufacturer or importer knows that a customer is using a chemical substance for other than research purposes, he should not report that chemical substance. The special reporting period after publication of the initial inventory is expressly to provide an opportunity for people to supplement the initial inventory with chemical substances which are manufactured or processed for commercial purposes but which were not reported by manufacturers or importers. The customers of a company selling primarily research chemical substances could report any chemical substance that belongs on the inventory at that time.

**Comment 49:** The provision that small quantities for research and development must be used by, or directly under the supervision of a technically qualified individual, should be deleted.

**Response:** The Administrator disagrees with this comment. As discussed in response to comments 43, 44, 45, and 46 above. Congress clearly intended research and development chemicals, that are exempted from the inventory and from premanufacture notification requirements, to be used only by, or under the supervision of technically qualified individuals.

**Comment 50:** Professional certification should be added as a factor which would establish that a person is "technically qualified."

**Response:** EPA believes that this factor is already included in the definition of tech-

nically qualified individual. EPA presumes that professional certification would be based on the education, training, or experience of the individual. Accordingly, it would be redundant to include professional certification as a separate factor. Persons could cite their professional qualifications as evidence of being a "technically qualified individual."

**Comment 51:** Can the responsibilities included within the definition of "technically qualified individual" be delegated to more than one person?

**Response:** The Agency recognizes that some manufacturers may designate an individual other than the person actually conducting or directly supervising the research or development as the person responsible for making safety assessments and clearances with respect to the procurement, storage, use, and disposal of the chemical substance. Such responsibilities can be delegated, so long as all phases of the research and development of a product are conducted, or directly supervised by a person who because of his education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance.

For example, one person may be responsible for analyzing the properties of a chemical substance used as a glue to back a rug, while a second person may have responsibility for determining how to dispose of the rug samples that contain the experimental glue. Similarly, there may be a duly authorized individual responsible for procurement of research chemical substances who is different from the technically qualified individuals who conduct the experiments with those chemical substances. So long as each of these persons is professionally qualified, the "technically qualified individual" definition will be fulfilled.

#### Byproducts

**Comment 52:** All byproducts should be required to be reported for the inventory.

**Response:** The Administrator disagrees with this comment. As a matter of policy, the Agency has decided that byproducts which have no commercial purpose should not be reported for the inventory. And, as is discussed in response to comment 54, byproducts which have some commercial value are not required to be reported for the inventory. Insofar as these wastes are hazardous, EPA intends to require reporting of them under the Resource Conservation and Recovery Act (Pub. L. 94-580) next spring, or under TSCA section 8(a)(2) during subsequent phases of reporting. Moreover, the provisions of TSCA sections 8(c), 8(d), and 8(e) are applicable to byproducts and the Agency will use the authorities of TSCA sections 4, 6, and 7 to prevent and reduce any unreasonable risks posed by byproducts.

**Comment 53:** The definition of byproduct in the March 9, 1977, proposal is confusing. Chemical substances formed as a result of secondary chemical reactions, including those that occur upon end-use or in storage, are not "byproducts."

**Response:** EPA recognizes that the definition of byproduct in the March 9 proposal was confusing. The August 2 proposal and these final regulations (§ 710.2(g)) have redefined "byproduct" to include only those chemical substances produced without separate commercial intent during the manufacture or processing of other chemical substances or mixtures.

The legislative history of TSCA makes clear that these secondary chemical substances are not to be subject to the inventory and premanufacture notification requirements because they are not manufactured for commercial purposes per se. S. Rep. No.

94-698, 94th Cong. 2d Sess. 19 (1976). Accordingly, section 710.4(d)(2) of these regulations excludes these substances from these requirements.

**Comment 54:** Should slags which have some commercial value and that are byproducts in the manufacture of another substance be reported for the inventory?

**Response:** Section 710.4(d)(2) of these regulations provides that byproducts that have some specific kinds of commercial value may be reported for the inventory, although there is no requirement that they be so reported. Byproducts that have no commercial value may not be reported for the inventory.

**Comment 55:** Persons who extract component chemical substances from byproducts should not be required to report those chemical substances.

**Response:** The Administrator agrees with this comment. Persons who recover chemical substances from byproducts of the manufacture or processing of other chemical substances, mixtures, or articles would be processors of the chemical substances and need not report for the inventory. There is no requirement that these persons report any chemical substance which is extracted or separated from a byproduct, including by means of heat or a chemical reaction, if the chemical substance that is recovered is actually present in the byproduct or was an intermediate used in the manufacture of the byproduct, and if also, to the best of the knowledge of the person recovering the substance, the manufacturer of the substance is reporting the substance for inclusion on the inventory.

#### Articles

**Comment 56:** Can articles be reported for the inventory?

**Response:** Articles as defined at § 710.2(f) will not be included on the inventory. The inventory is a list of chemical substances manufactured or processed for a commercial purpose in the United States. Chemical substances of which articles are comprised can, however, be reported for the inventory.

**Comment 57:** What are the reporting requirements with respect to manufactured items containing fluids or particles?

**Response:** The definition of "article" at § 710.2 excludes fluids and particles regardless of shape or design. Accordingly, all fluids and particles will either be a "mixture" or "chemical substance" for the purposes of TSCA. Any fluid or particle which is a chemical substance should be reported for the inventory. See also response to comment 21.

**Comment 58:** The definition of "article" should be modified to include products such as films and batteries which undergo chemical changes during their end uses.

**Response:** The Administrator agrees with this comment and has amended clause 3 of the definition to include within the meaning of "article" a manufactured item "which either has no change of chemical composition during its end-use or only those changes in composition which have no commercial purpose separate from the article of which it is a part and that may occur as described in § 710.4(d)(5)." The provision in § 710.4 is an exclusion for chemical substances which are the result of reactions that may occur upon end-use of other chemical substances, mixtures, or articles. Under this revised approach, batteries, photographic films, matches, flares, ablative nose cones, brake linings, and other such products are considered "articles."

**Comment 59:** Fibers, filaments, and whiskers should be considered articles.

**Response:** As defined in § 710.2(f), fibrous materials may be considered articles if (1) their end-use functions depend in whole or

in part upon their shape or design and (2) they are functional in their end-use without a change of chemical composition except for changes that have no commercial purpose separate from the articles of which they are a part. If a person shapes a chemical substance into a filament or fiber, he would be a processor of that substance. The chemical substance would be reportable by the manufacturer. The filament or fiber or whisker would be an article and could not be reported. However, if that fibrous material was intended to be used as an intermediate in the manufacture of another chemical substance, it would not be considered an article. It would be considered a chemical substance (or mixture). Particles are not articles whether they are round or asymmetric. If a whisker or other fibrous material may be used as a particle in its subsequent processing, it would not be considered an article.

**Comment 60:** Chemical substances used in the finishing process of an article should not be excluded from the inventory. Dyes and fire retardants are two examples of substances which should be reported.

**Response:** The Administrator agrees with this comment. There has been some confusion over the intent of the exclusion in §710.5(d)(6) of these regulations. The exclusion is for chemical substances that are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the mixture or article of which they may be part.

Dyes and fire retardants are chemical substances, manufactured for distribution in commerce as chemical substances, and therefore do have a separate commercial purpose. These substances should be reported by their manufacturers for inclusion on the inventory. The exclusion in §710.4(d)(6) is for chemical substances formed when the dye or fire retardant reacts with fibers of a garment or other article upon end-use of those substances by a processor. These reaction products must not be reported.

#### Impurities

**Comment 61:** Chemical substances should be listed on the inventory with respect to their impurities.

**Response:** The Administrator disagrees with this comment. The Agency has determined that as a matter of policy, this first inventory should not distinguish among chemical substances which are identical except with respect to their impurities. The Agency recognizes the potential hazards of some impurities and intends to use the alternative authorities of sections 4, 6, 7, and 8 to prevent and reduce any unreasonable risks posed by impurities. In addition, in the future EPA may revise the inventory to take impurities of a chemical substance into account.

#### CHEMICAL SUBSTANCES INCLUDED IN THE INVENTORY

**Comment 62:** Since customer demand runs in cycles, some provision should be made to allow companies to report chemical substances which they manufactured for a commercial purpose more than three years ago and plan to produce again.

**Response:** The Administrator agrees in part with this comment. Section 8(b) of TSCA provides that a chemical substance may not be included on the inventory if it was not manufactured or processed within three years before the effective date of these regulations. Accordingly, §710.3(a)(3)(ii) of these regulations, provides that if a person manufactured a substance for a commercial purpose before January 1, 1975, he may still report

the substance for the inventory if he certifies that the substance was processed after January 1, 1975. If a manufacturer neither manufactured a chemical substance nor can certify that the substance was processed within the past three years, he may not report the substance for the inventory, even if he plans to produce it again in the future. If the substance is not reported for the inventory by the manufacturer or by another manufacturer or processor, manufacturers will have to submit premanufacture notification on the substance 90 days before manufacturing it again.

**Comment 63:** Manufacturers should be able to report chemical substances manufactured since July 1, 1974, as provided in the March 9, 1977, proposal.

**Response:** The Administrator disagrees with this comment. The July 1, 1974, date was included in the March 9, 1977, proposal on the assumption that final inventory reporting rules would be promulgated by July 1977. Section 8(b) of TSCA clearly provides that the inventory may not include any chemical substance which was not manufactured or processed within 3 years of the effective date of these rules. As discussed in response to comment 62, a manufacturer may report a substance for the inventory if it was manufactured before January 1, 1975, so long as it was processed after January 1, 1975.

#### Test Marketing

**Comment 64:** The Administrator has no authority to exclude chemical substances presently undergoing test marketing from the initial inventory.

**Response:** Any chemical substance which is manufactured or imported for test marketing purposes is eligible for inclusion on the inventory. This is made clear by the definition of the term "manufacture or import for commercial purposes" at §710.2(p). After the effective date of the premanufacture notification requirements of section 5(a)(1)(A), a manufacturer may not test market a new chemical substance without first either providing the premanufacture notification required by that section or obtaining an exemption from the requirement under section 5(h)(1) of the Act.

**Comment 65:** The critical factor in distinguishing the "development phase" of a product from its "test marketing" phase is that the latter phase contemplates a sale. The word "sale" must be included in the definition of "test marketing" because accepted and ordinary usage of the phrase involves the sale of a product under practical competitive conditions.

**Response:** The Administrator does not agree with this comment. Sale of a product does not always distinguish its development phase from its test marketing phase. The Congress itself recognized that "the fact that the other industrial user may pay the costs for the substance does not necessarily signal the end of the development period." H.R. Rep. No. 94-1341, 94th Cong., 2d Sess. 30 (1976).

For the purposes of these regulations, research and development activity will be differentiated from test marketing primarily by the greater degree of control maintained by the manufacturer and the greater technical qualifications of those handling and supervising the use of the substance during the research and development phase. Distribution of the product during the test marketing phase generally removes the product, its use, and its disposal from the direct supervision of the manufacturer. (See response to comments 43-51.)

**Comment 66:** EPA should place restrictions on both the population and geography which may be exposed to products in test marketing and should require labeling of products to indicate potential hazards.

**Response:** The Administrator has authority under section 5(h)(1) to impose such restrictions on test marketing of a chemical substance as are necessary prior to exempting the chemical from the premanufacture notification requirements. In addition, the Administrator will use the authorities of sections 4, 6, and 7 of the Act to prevent unreasonable risks to man and the environment.

#### Intermediates

**Comment 67:** The term "intermediate" should exclude intermediates that are merely "isolatable", and are never encountered in the environment. The identification of these intermediates will often require highly trained chemists and will significantly increase the costs of complying with the reporting requirements.

**Response:** The Administrator agrees with this comment and the definition of "intermediate" at §710.2(n) has been amended accordingly. Chemical substances which are not removed from the equipment in which they are manufactured are not considered "intermediates" for the purposes of these regulations and are excluded from the inventory by §710.5(d)(8). EPA will require notification under section 5 for any chemical substance which is not on the inventory and which, after the date of the premanufacture notification requirements, is isolated, or intentionally removed from the equipment in which it was manufactured. A manufacturer may, however, apply for an exemption from this requirement under section 5(h)(5) if the intermediate exists temporarily and there is no, and will not be any, human or environmental exposure. Chemical substances excluded from the inventory by §710.4(d)(8) are considered to be manufactured or processed for a commercial purpose for the purposes of section 8 of the Act.

**Comment 68:** The definition of "intermediate" in the March 9, 1977 proposed regulations is more descriptive of an "impurity." An "intermediate" should refer to a chemical substance that is both created and totally consumed during the chemical reaction process. This description would provide a meaningful distinction between an "intermediate," a "byproduct," and an "impurity."

**Response:** The Administrator agrees in part with this comment and has substantially revised the definition of "intermediate." The purpose of the definitions under these regulations is to clarify which chemical substances are included and which are excluded from the inventory. The Administrator does not agree that the term "intermediate" should be restricted to chemical substances that are totally consumed in chemical reaction processes. A chemical substance may be an intermediate and also appear later as a byproduct or as an impurity. In such circumstances, the substance should be reported for the inventory.

Under these definitions, the essential difference between a byproduct and an intermediate is that the intermediate is consumed, in whole or in part, in a chemical reaction used for the intentional manufacture of other chemical substances, or is intentionally present for the purpose of altering the rate of such reaction(s). A byproduct may be formed and then consumed in whole or in part during the reaction sequence but is not an "intermediate" unless it is consumed in whole or in part in chemical reactions used for the intentional manufacture of other chemical substances or is intended to alter the rate of such reactions.

Impurities are defined as chemical substances which are unintentionally present with another chemical substance. While intermediates often appear as trace impurities in a final product, they are in general dis-

tinguished from impurities in that they serve an intentional purpose in a reaction sequence.

**Comment 69:** Chain transfer agents or cross linking agents used in the manufacture of polymers should be considered intermediates.

**Response:** The Administrator agrees with this comment. Cross linking agents and chain transfer agents which are used in the manufacture of polymers are considered to be processed for commercial purposes and should be included on the inventory. The processor who buys such substances for use in the manufacture of polymers need not report such substances. However, he should ensure that the substances are included on the initial inventory or report these substances during the special reporting period for the revised inventory.

Section 710.5(c) requires listing in the description of a polymer at least those monomers used at greater than two percent (by weight) in the manufacture of the polymer. In a similar fashion, a manufacturer would list, as part of the polymer description, those cross linking, chain transfer and other reactive agents which are present at greater than two percent (by weight) in the manufacture of the polymer. Additives such as plasticizers and emulsifiers which are only entrained in the polymer are considered to be components of a mixture and should not be considered to be components of the polymer. See response to comments 77-82 on reporting of polymers.

**Comment 70:** In the manufacture of polymers, there are literally thousands of intermediates deliberately present in the reaction sequence. The process may be interrupted, occasionally, for examination and testing, at which point chemically reacted substances are removed. Such substances should not be considered "intermediates" for the purposes of these regulations and should not be reported for the inventory.

**Response:** The Administrator agrees, in part, with this comment. If a chemical substance satisfies the definition of "intermediate" at § 710.2(n) of these regulations, for the purposes of these regulations, it is an intermediate. However, an intermediate may also fall within the exclusion from these regulations at § 710.4(c) (3) for "small quantities for research and development." If an "intermediate" is a "small quantity for research and development" it is excluded from the inventory. Hence the removal of small quantities of a chemical substance from the equipment in which it was manufactured does not make that chemical substance a reportable "intermediate" if the amount removed is used solely for testing or research purposes described in § 710.2(y).

**Comment 71:** The inclusion of "intentionally present catalysts" under the definition of intermediates in the March 9 proposal is confusing.

**Response:** The Administrator agrees with this comment and has revised the term "intermediate" at § 710.2(n) to include "any chemical substance which is intentionally present for the purpose of altering the rate of (such) chemical reaction(s)." This definition of the term "intermediate" is consistent with common usage. It considers "catalysts" as "intermediates".

#### Naturally Occurring Substances

**Comment 72:** Which of the following substances would be considered "naturally occurring substances," and therefore be excluded from the reporting requirements: natural latex; "natural rubber"; enzymes; and calcinated clays?

**Response:** The natural latex obtained from certain trees is considered a naturally occurring substance. However, the "natural rubber" which is formed after chemical co-

agulants are added to the latex would not be considered in the category of "naturally occurring substances". Thus, importers of "natural rubber" must report under these regulations. Enzymes are not included in this category unless they were extracted from nature only by the means described in § 710.4 (b). And, calcinated clays which are formed by heating naturally occurring clay are not included in this category because such heating is not done solely to remove water.

**Comment 73:** The category of "naturally occurring substances" should be expanded to include those substances which are extracted from other naturally occurring substances using any solvent, not just water.

**Response:** The Administrator disagrees with this comment. EPA has decided that the category should contain only those substances which are removed from nature essentially by natural means. Using water to extract a chemical substance from a naturally occurring substance is considered a natural means of removal. Using other solvents is not considered a natural means of removal.

**Comment 74:** The category for naturally occurring substances should include substances that are processed by electrostatic means.

**Response:** The Administrator agrees with this comment. In an electrostatic separation, small particles are removed from a liquid or gas stream. The process is essentially analogous to a filtration or gravitational separation. Substances which are processed by this means fall within the naturally occurring substances category.

**Comment 75:** How does EPA intend to regulate naturally occurring chemical substances which may be harmful?

**Response:** The Agency will use the authorities contained in section 8(a) of the statute to require reporting on a selective basis from manufacturers and processors of naturally occurring chemical substances. In addition, the Agency will use the authorities of sections 4, 6, and 7 of TSCA to identify and regulate any unreasonable risks to health or the environment presented by naturally occurring chemical substances.

#### INVENTORY REPORTING PROCEDURES

**Comment 76:** EPA should form a group which can help industry answer specific questions concerning filling out the reporting forms. Responses should be available within 10 days and signed by an authorized individual.

**Response:** The Office of Industry Assistance in the Office of Toxic Substances and the staffs of the Agency's Regional offices will be prepared to answer specific questions concerning the inventory reporting requirements. EPA will make every effort to respond to inquiries as quickly as possible.

#### Reporting of Polymers

**Comment 77:** Polymers should be required to be identified with respect to their constituent monomers present at greater than two percent with the option of reporting those monomers present at less than two percent. All monomers used in the manufacture of the polymer should be reported for the inventory.

**Response:** The Administrator agrees with this comment. Section 710.5(c) of the regulations is written to accomplish this result.

**Comment 78:** Some commenters argued that polymers should be required to be identified with respect to the constituent monomers present at greater than five percent. Other commenters argued that every constituent monomer of a polymer should be reported.

**Response:** The Administrator disagrees with these comments. In the interest of hav-

ing an inventory that accurately reflects the identities of the polymers in commerce, EPA felt that requiring reporting of only those constituent monomers present at five percent or greater would be unsatisfactory. On the other hand, since every monomer must be identified on the inventory even though not reported as part of a specific polymer, EPA did not believe it was essential to require reporting of each polymer with respect to all of its constituent monomers. Moreover, EPA recognizes important advantages in requiring manufacturers of polymers to identify only those monomers present at two percent or more.

First, the principal identities of many polymers that might have been claimed to be confidential if required to be fully disclosed will be included on the inventory. Further, it is sometimes difficult to distinguish what chemical substances present at less than two percent in a polymer would be appropriately considered a reportable monomer or merely an impurity. Finally, small variations among polymers due to minor process changes, for example, will not be subject to premanufacture notification provided, the polymer does not contain a new chemical substance.

EPA recognizes that for the purpose of evaluating potential toxicity, the proposed description of polymers is insufficient. EPA intends to obtain detailed information with respect to specific classes of polymers under section 8(a). In addition, EPA will consider possible refinement of descriptions of polymers for purposes of the inventory in the future. However, because potential toxicity may be dependent on properties such as solubility, molecular weight distribution, and crystallinity, it is unlikely that even with further revisions, the listing of monomers would be sufficient to indicate the relative potential toxicity of the polymers.

Finally, these regulations do not exempt from the inventory any chemical substance which is manufactured for commercial purposes as a monomer, regardless of its percentage use in the manufacture of polymers. Additives which are not intended to be part of polymeric chemical substances should not be reported as part of the description of polymers, but should be included separately on the inventory as chemical substances.

**Comment 79:** Some numerical molecular weight should be determined for purposes of distinguishing reactive and relatively non-reactive polymers and copolymers. Above a certain specified molecular weight, relatively non-reactive polymers should not be listed individually, but only the monomers that comprise these polymers in various combinations should be listed. Below that weight, each polymer or copolymer should be listed separately with respect to its constituent monomers.

**Response:** The Administrator believes that such an approach should be investigated. While it is not feasible to adopt such an approach for the present inventory, EPA may revise the inventory accordingly once an appropriate test method is adopted to ensure consistency in measuring polymer weights.

**Comment 80:** Any chemical substance known as a polymer should be excluded from the inventory, provided that each constituent monomer and precursor chemical is reported.

**Response:** The Administrator does not agree with the proposal to exclude reporting of all polymers. EPA does recognize, however, that non-volatile or inert polymers above some particular average molecular weight could perhaps be handled differently. As mentioned in response to comment 79 above, EPA intends to investigate distinguishing polymers on the basis of their average molecular weight and possibly modifying the inventory in the future.

**Comment 81:** How should the weight of a monomer be calculated and what is meant

by a monomer present at a certain "weight percent" of a polymer?

**Response:** For purpose of the inventory reporting requirements, the percent (by weight) of a monomer is the weight of the monomer charged into the reactor and not the weight incorporated into the polymer. The weight of the monomer should be expressed as a percentage of the weight of the polymeric chemical substance manufactured.

**Comment 82:** If a polymer listed on the inventory contains five monomers, for example, a new polymer with four of those five monomers should not be considered a "new chemical substance" for the purposes of section 5(a)(1)(A).

**Response:** The Administrator disagrees with this comment. If someone created a polymer that contained fifty different monomers which were added in insignificant quantities merely to include them as part of that reported polymer, a manufacturer could then create thousands of polymeric combinations based on those fifty monomers without reporting them for the inventory or submitting premanufacture notification.

#### Inventory Reporting Forms

**Comment 83:** All forms should begin with a certification to the effect that "to the best of my knowledge and belief, I certify that . . ."

**Response:** The Administrator agrees with this comment and has modified the forms accordingly.

**Comment 84:** It should not be necessary to report both chemical names and Chemical Abstracts Service (CAS) numbers on Form B.

**Response:** The reason that EPA requires a manufacturer to report both a chemical name and the Chemical Abstract Service Registry number on Form B is to ensure that a manufacturer has reported correctly. If EPA required only reporting of the seven-digit CAS numbers, EPA would have no means to check whether a manufacturer correctly reported that number.

**Comment 85:** It should be possible to fill out all forms on computer print-out or tape.

**Response:** Manufacturers may report chemical substances that have CAS registry numbers by computer print-out or tape. Instructions for reporting in this manner are included in the instruction booklet accompanying the forms.

**Comment 86:** The instructions for reporting should make clear that complex, undefined chemical substances may be reported by describing the reaction process used to manufacture the substances.

**Response:** EPA recognizes that it is often difficult to describe complex reaction products whose composition is variable or unknown. Many of these substances are commonly described by generic terms such as coal tar, shellac, or vegetable extracts. For purposes of the inventory, manufacturers should report as specifically as possible, using generic terms and a description of the method used in the final reaction sequence to produce the reported substance. EPA will publish detailed instructions in "Reporting for the TSCA Inventory."

**Comment 87:** Form D is an excellent idea which will be very useful for processors and others who buy trademarked chemicals whose composition is unknown to them. It should be updated frequently.

**Response:** EPA encourages manufacturers who report for the initial inventory to include on Form D the trademarks, whether registered or not, by which chemical substances reported for the inventory are known. A manufacturer may report a trademark for a product which is a chemical substance, a mixture or an article containing a chemical substance. As provided in the

instructions to Form D, a manufacturer who chooses to report, must certify that all the chemical substances which comprise the trademarked product have been reported for the inventory, either by him or by someone else.

EPA recognizes that processors and users of chemical substances do not always know the identities of the substances they purchase and thus, may have difficulty determining whether or not the chemical substances they purchase are included on the inventory. Processors could individually request suppliers to certify that the substances they sell are included on the inventory. The Agency hopes to ease this burden somewhat by providing manufacturers who sell their products under a trademark an opportunity to certify that the chemical substances contained in the particular trademarked product have been reported for the inventory. Any false certification would subject a manufacturer to criminal penalties under 18 U.S.C. 1001.

The usefulness of the trademark list is, however, limited. EPA recognizes that the composition of any particular trademark product may vary over time. Further, the Agency is not now requiring manufacturers who choose to report their trademarks to link the product name with specific chemical substances. Accordingly, the Agency will not be able to verify the accuracy of the trademark list.

Because of the limited utility of the trademark list, the Agency does not now intend to update it. The list is designed to assist processors and users in reporting for the revised inventory. The Agency will be studying the continuing problem presented by the fact that persons in the chemical industry do not always know the identity of the substances they purchase.

#### WHEN TO REPORT

**Comment 88:** Manufacturers and processors need more than 90 days to report all the information required by these regulations.

**Response:** The Administrator agrees with this comment. Section 710.6(a) provides manufacturers and importers until May 1, 1978 to report for the initial inventory. Section 710.6(c) provides processors and users of chemical substances 210 days to report for the revised inventory. The Agency encourages persons reporting for the inventory to stagger their submissions throughout the reporting period so that they can be processed in a timely manner.

**Comment 89:** A manufacturer should be able to add new chemicals to the inventory any time prior to the start of premanufacture notification.

**Response:** The Administrator agrees with this comment. Section 710.6(b) provides this authority. A manufacturer or importer of a chemical substance in bulk may report a new chemical substance until 30 days after publication of the initial inventory. An importer of a chemical substance as part of a mixture or article may report a new chemical substance for the inventory until 30 days after publication of the revised inventory.

**Comment 90:** Manufacturers and importers of chemical substances should be allowed to report for the revised inventory. Premanufacture notification should not begin until after publication of the revised inventory.

**Response:** The Administrator disagrees with this comment. Postponement of premanufacture notification until after publication of the revised inventory would delay the effectiveness of this provision of the Act for an unacceptable period of time. The revised inventory may not be published until November 1979 or later.

**Comment 91:** The Administrator should provide by regulation that failure to report for inclusion in the inventory for "good

cause" will not subject the manufacturer to the premanufacture notification requirements of section 5(a)(1)(A).

**Response:** The Administrator disagrees with this comment. Such a provision is not appropriate for these inventory reporting regulations. EPA does recognize, however, that given the large volume of information that is to be compiled and transmitted, it is inevitable that there may be some clerical or technical errors made in reporting chemical substances for the inventory. Accordingly, the note at § 710.1(b) of these regulations provides that as a matter of traditional Agency policy, EPA does not intend to concentrate its enforcement efforts on insignificant clerical errors in reporting. Instead, EPA will give priority to bringing enforcement actions against persons who (1) report false information, (2) report for inclusion on the inventory chemical substances which are excluded under § 710.4(c) of these regulations, (3) fail to report, or (4) fail to maintain records documenting reported information.

**Comment 92:** In assessing any penalty on a manufacturer, the impacts on processors and users of the chemical substance(s) should be considered.

**Response:** The Administrator agrees with this comment. Section 16(a)(2)(B) of the Act provides that in assessing any penalty the Administrator must take into account several factors. In assessing a civil penalty against a manufacturer, the Administrator as a matter of policy will consider the effect of the action on persons who process and use that chemical substance.

#### CONFIDENTIALITY

##### Identity of Chemical Substance

**Comment 93:** Some chemical identities are entitled to confidential treatment for purposes of the TSCA inventory. Any submitter should be allowed to claim that any chemical identity is confidential for the inventory.

**Response:** The Administrator agrees with this comment. The general approach EPA will take to confidentiality of specific chemical identities for purposes of the inventory is set out in the preamble and § 710.7 of these regulations. In choosing this approach EPA had to balance the competing concerns of section 14 and sections 8(a) and 5(b). The reasons for taking this approach follow.

The inventory is a list of chemical substances manufactured (including imported) or processed for a commercial purpose. Many chemical substances have been developed and synthesized for which no commercial purpose has been found. The fact that someone has found a commercial purpose for a particular chemical substance may be a confidential trade secret. Placement of the specific chemical identity on the inventory would announce that fact to potential competitors who might be able to narrow their research activities. This problem would be further compounded if the chemical substance were newly synthesized and known only to the person reporting it to EPA or if the substance were patentable, in which case inclusion on the inventory might constitute a publication and limit the person's patent rights.

Were there no requirement in section 8(b) of TSCA to publish a list of chemical substances manufactured and processed for commercial purposes, there is no doubt that the fact that certain substances are manufactured or processed for commercial purposes would be confidential under traditional trade secrets law and case law under the Freedom of Information Act fourth exemption (5 U.S.C. 552(b)(4)). Section 14(a) of TSCA states that any information reported to EPA under TSCA that is exempt from disclosure under 5 U.S.C. 552(b)(4) may not